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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,539	11/13/2003	Loran Paprocki	47563.0008	9183

57600 7590 05/31/2007

HOLLAND & HART LLP
60 E. SOUTH TEMPLE
SUITE 2000
SALT LAKE CITY, UT 84111

EXAMINER	
EREZO, DARWIN P	
ART UNIT	**PAPER NUMBER**
3731	
MAIL DATE	**DELIVERY MODE**
05/31/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/712,539	PAPROCKI, LORAN	
	Examiner	Art Unit	
	Darwin P. Erezo	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) *29-37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/16/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Invention I in the reply filed on 2/28/07 is acknowledged.

2. Claims 29-37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 2/28/07.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Independent claim 1 recites that the block and tackle is disposed in the closure device and anchored to the proximal end. However, the specification only shows the block and tackle assembly **160** being disposed within the closure device **102** between the proximal and distal ends, as seen in Fig. 3A. The specification does not show the block and tackle **160** being anchored to the proximal end. There is only support in the specification for a portion of the block and tackle (the cap) to be located at the proximal

end of the closure device. Therefore, one of skilled in the art would not know how to make/or use the invention as claimed.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 14-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claim 14 recites the limitation "the second filament" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-16 and 18-28 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,662,681 to Nash et al.

(claim 1) Nash discloses a tissue puncture closure assembly (as seen in Figs. 1-4), comprising:

a closure device **106** having a distal and a proximal end (see Fig. 1);

a block and tackle (**36,110**) disposed in the closure device and anchored to the proximal end (block and tackle is being interpreted as a series of pulleys and cables; as

seen in Fig. 1, portion **110** is resting against the proximal end of the closure device **106**);

a first filament **34** extending from portion **36** of the block and tackle;

an anchor **32** attached to the first filament at the distal end of the tissue puncture closure device;

a sealing plug **30** attached to the first filament between the anchor and the block and tackle.

(claim 2) Portion **36** of the block and tackle is a plate having a plurality of holes disposed therein with a second filament **34D** anchored to the proximal end of the closure device and looping through at least two of the plurality of holes.

(claim 3) The second filament **34D** terminates with a pull-tab extending from the proximal end of the tissue puncture closure device (the top portion of the element **110**).

(claim 4) The plate comprises at least two holes extending therethrough, wherein the spacing between each holes at each end of plate is viewed as a riser. It is noted that the claim limitation does not clearly provide any structure for the term "riser".

(claim 5) The first filament is slidingly attached to the anchor and the sealing plug.

(claim 6) The first filament extends distally from portion **36** of the block and tackle through the sealing plug and the anchor, back proximally toward the block and tackle, and is tied onto itself in a slip knot disposed between the block and tackle and the sealing plug.

(claim 7) The plurality of holes comprises three holes (see Fig. 2).

(claim 8) The first filament, the sealing plug, and the anchor are biologically resorbable (col. 8, lines 16-35).

10. (claims 9 and 10) See insertion sheath **102** having a fold in the distal end of the flexible tube (Fig. 1).

(claim 11) Nash discloses an internal incision sealing device comprising:

an internal component **32** configured to be positioned against an internal portion of an incision;

an external component **30** configured to be positioned at an external portion of the incision,

wherein the external component is attached to the internal component by a first slip-knotted filament **34B** such that tension on the first filament compresses the internal component and external component together; and

a block and tackle (**36,110**) disposed within the internal incision sealing device and operatively connected to the internal and external components (block and tackle is being interpreted as a series of pulleys and cables).

(claim 12) The block and tackle (**36,110**) creates a mechanical advantage such that the tension on a second filament traversing the block is multiplied and applied to the first filament, causing the slip knot to slide and compress the internal and external components together across the incision.

(claim 13) The internal incision is capable of being any type of incision, including an arteriotomy.

(claim 14) The second filament **34D** is fixed to a cap of the sealing device at a first end, and free at a second end (see Fig. 2),

(claim 15) The second end further comprises a pull-tab (the top portion of element **110**).

(claim 16) The block and tackle comprises at least two loops, creating at least a four to one mechanical advantage.

(claim 18) The internal component is an anchor shaped to advance in a low profile configuration through an insertion sheath, and automatically rotate into an expanded configuration upon exit from the insertion sheath and retraction of the sealing device.

(claim 19) The external component is a collagen sponge.

(claim 20) The internal component, the external component, and the first slip-knotted filament are biologically resorbable (col. 8, lines 16-35).

(claim 21) The first slip-knotted filament is attached or looped through the block and tackle, and threads through the external component, through a hole in the internal component, and is knotted proximal of the external component.

(claim 22) Portion **36** of the block and tackle is a plate with at least two holes extending through.

(claim 23) The plate comprises at least two holes extending therethrough, wherein the spacing between each holes at each end of plate is viewed as a riser. It is noted that the claim limitation does not clearly provide any structure for the term "riser".

(claim 24) Nash discloses a sealing device, comprising:

an anchor **32** shaped to advance in a low profile configuration and automatically rotate into an expanded configuration when retracted;

a collagen sponge **30** connected in a loop to the anchor by a biologically resorbable filament; wherein tension on the biologically resorbable filament compresses the collagen sponge and the anchor together; and

a block and tackle **36** operatively connected to the biologically resorbable filament for generating a mechanical advantage (block and tackle is being interpreted as a series of pulleys and cables).

(claim 25) The block and tackle is attached to a cap **110** of the sealing device via a second filament **34D**.

(claim 26) The second filament is fixably secured to the cap, loops between the block and the cap at least once, and extends out of the cap.

(claim 27) The block and tackle comprises a plate **36** with at least two holes extending through.

(claim 28) The plate comprises at least two holes extending therethrough, wherein the spacing between each holes at each end of plate is viewed as a riser. It is noted that the claim limitation does not clearly provide any structure for the term "riser".

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nash et al.

Nash discloses the cap **110** being crimped onto the second filament **34D**. Nash is silent with regards to securing the cap onto the filament via a stop plug. However, it would have been an obvious matter of design choice to one of ordinary skill in the art at the time the invention was made to use any type of securing means, such as a stop plug or crimping, to secure the cap onto the filament because these means are well known in the art. Furthermore, either type of means would the same function of securing the cap onto the filament.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erezo whose telephone number is (571) 272-4695. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Darwin P. Erezo/
Examiner
Art Unit 3731

de